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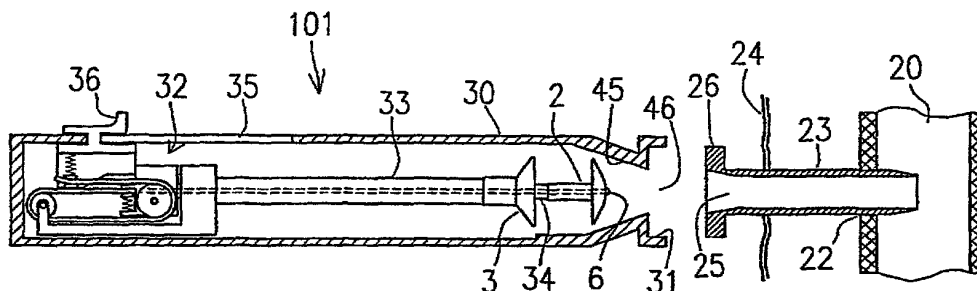
— *With international search report.*

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND**



(57) Abstract: A tool (101) is provided for inserting and mating two plug members (2, 3) of a sealing device (1) for closing a wound in the wall of a vessel by placing the distal plug member (2) of the sealing device inside the vessel and the proximal plug member (3) on the outside of the vessel. The distal plug member is provided with an elongated retracting means (6) extending from the distal plug member. The tool comprises a gear mechanism (32) coupled to the retracting means for converting a movement of the tool in a proximal direction away from the wound (22), when the distal plug member is anchored in the vessel (20), to a pushing movement for moving the proximal plug member in a direction towards the distal plug member in response to a stretching force in the retracting means.

WO 00/78226 A1

FORM PTO-1390 (Modified) (REV 5-93)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				030481-0183	
				U.S. APPLICATION NO. (If known, see 37 CFR 1.51) Unassigned 10/018137	
INTERNATIONAL APPLICATION NO. PCT/SE99/01114		INTERNATIONAL FILING DATE 06/18/1999		PRIORITY DATE CLAIMED 06/18/1999	
TITLE OF INVENTION A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND					
APPLICANT(S) FOR DO/EO/US Dan AKERFELDT, Per EGNELOV and Fredrik PREINITZ					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</p> <p>4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> has been transmitted by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</p> <p>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). <input type="checkbox"/> have been transmitted by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>11. <input checked="" type="checkbox"/> Applicant claims small entity status under 37 CFR 1.27 .</p>					
Items 12. to 17. below concern other document(s) or information included:					
<p>12. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>13. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>14. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> Other items or information:</p>					

U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.50) Unassigned 10/018137		INTERNATIONAL APPLICATION NO. PCT/SE99/01114		ATTORNEY'S DOCKET NUMBER 030481-0183	
18. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
Basic National Fee (37 CFR 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO.....\$890.00					
International preliminary examination fee paid to USPTO (37 CFR 1.482)\$710.00					
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))\$740.00					
Neither international preliminary examination fee (37 CFR 1.482) nor International search fee (37 CFR 1.445(a)(2)) paid to USPTO \$1,040.00					
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)\$100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$1,040.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 20 Months from the earliest claimed priority date (37 CFR 1.492(e))				\$130.00	
Claims	Number Filed	Included in Basic Fee	Extra Claims	Rate	
Total Claims	11	- 20	= 0	× \$18.00	\$0.00
Independent Claims	3	- 3	= 0	× \$84.00	\$0.00
Multiple dependent claim(s) (if applicable)				\$280.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,170.00	
Reduction by ½ for filing by small entity, if applicable.				\$585.00	
SUBTOTAL =				\$585.00	
Processing fee of \$130.00 for furnishing English translation later the 20 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	
TOTAL NATIONAL FEE =				\$585.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					
TOTAL FEES ENCLOSED =				\$585.00	
				Amount to be: refunded \$	
				charged \$	
<p>a. <input checked="" type="checkbox"/> A check in the amount of \$585.00 to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. <u>19-0741</u> in the amount of \$585.00 to the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0741</u>. A duplicate copy of this sheet is enclosed.</p>					
<p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p>					
<p>SEND ALL CORRESPONDENCE TO:</p> <p>Foley & Lardner Washington Harbour 3000 K Street, N.W., Suite 500 Washington, D.C. 20007-5143</p>					
				<p><i>Rhonda</i> 25,479 SIGNATURE</p> <p><i>Glenn</i> NAME GLENN LAW</p> <p>REGISTRATION NUMBER 34,371</p>	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 030481-0183

Applicant: Dan AKERFELDT

Title: A TOOL, A SEALING DEVICE, A SYSTEM AND A
METHOD FOR CLOSING A WOUND

Appln. No.: Unassigned

Filing Date: December 18, 2001

Examiner: Unassigned

Art Unit: Unassigned

#3/10

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior substantive examination of this application, it is respectfully requested that the following changes be implemented.

IN THE CLAIMS

Please replace claims 4 and 8 with the new versions shown on the following sheets. Please also add new claim 11.

*In accordance with 37 C.F.R. § 1.121(c)(ii), marked-up version(s) of the amended claim(s) are provided on separate sheet(s) at the end of this response under the heading of Marked-up Versions of Amended Claims.

4. (Once amended) The tool (101; 102) according to claim 1, **characterized in** that said tool comprises
- an outer feeding means (33; 133) for pushing the proximal plug member (3), said outer feeding means being provided with an axial through bore;
- an inner feeding means (34; 134) for pushing the distal plug member (2), said inner

feeding means being provided with an axial through bore for moveably receiving said retracting means (6), and said inner feeding means being disposed for movement in said bore of said outer feeding means;
said gear mechanism (32; 132) being coupled to said inner feeding means and said outer feeding means; and
a pushing means (36; 150) for pushing the gear mechanism (32; 132), the outer feeding means (33; 133) and the proximal plug member (3) with respect to the casing (30; 130) of the tool, in a direction towards the wound.

8. (Once amended) A system for closing a wound in a punctured vessel, **characterized in** that a sealing device according to claim 7 is inserted and mated by the use of a tool.

11. (Newly added) A system as for closing a wound in a punctured vessel according to claim 8, wherein the tool comprises a gear mechanism coupled to the retracting means for converting a movement of the tool in a proximal direction away from the wound, when the distal plug member is anchored in a vessel, to a pushing movement for moving the proximal plug member in a direction toward the distal plug member in response to a stretching force in the retracting means.

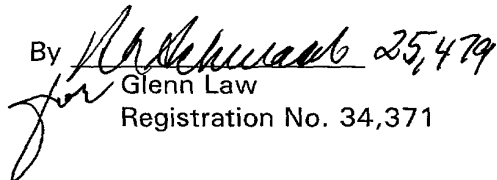
REMARKS

The amendments which are proposed in this response are deemed to improve the clarity and form of the claims. Support for the newly presented claim is found in at least originally presented claim 1.

Respectfully submitted,

Date: December 18, 2001

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MARKED-UP VERSIONS OF AMENDED CLAIMS

4. (Once amended) The tool (101; 102) according to [anyone of claims 1 through 3] claim 1, **characterized in** that said tool comprises
an outer feeding means (33; 133) for pushing the proximal plug member (3), said outer feeding means being provided with an axial through bore;
an inner feeding means (34; 134) for pushing the distal plug member (2), said inner feeding means being provided with an axial through bore for moveably receiving said retracting means (6), and said inner feeding means being disposed for movement in said bore of said outer feeding means;
said gear mechanism (32; 132) being coupled to said inner feeding means and said outer feeding means; and
a pushing means (36; 150) for pushing the gear mechanism (32; 132), the outer feeding means (33; 133) and the proximal plug member (3) with respect to the casing (30; 130) of the tool, in a direction towards the wound.

8. (Once amended) A system for closing a wound in a punctured vessel, **characterized in** that a sealing device according to claim 7 is inserted and mated by the use of a tool [according to anyone of claims 1 through 6].

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PCT/SE99/01114

7/12/01

TITLE

A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND

SCOPE OF THE INVENTION

- 5 The present invention relates to medical devices, and more specifically to a system for introducing a flexible two-piece wound closure plug in a punctured vessel of a human or animal body.

PRIOR ART

- 10 A sealing device for sealing an arterial puncture is described in US patent 5,350,399 to Erlebacher et al. A first closure member, that is resiliently expandable into a circular disc shape, is positioned within a punctured vessel. A second closure member, also being resiliently expandable into a circular disc shape, is movably fitted onto a guide means being integrally formed with the first closure member. The guide means has a saw tooth shape to hold the second closure member. The guide means also acts as a retracting means, i. e. a means for holding the first closure means towards the wound edge, when the first and second closure members are mated.
- 20 A tool for mating said first and second closure members is also disclosed in US patent 5,350,399. Initially, the first closure member and its integrated guide means is pushed into the artery through a percutaneous sheath, normally used for a treatment preceding the closure of the wound. Thus, the tool is not used for insertion of said first member. Then, the guide means of the first closure member is
- 25 passed through the tool, wherein the second closure member is stored in a folded state. Then, the second closure member is pushed out of the tool to be fitted onto the guide means of the first member by operating a trigger of the tool. The force with which the second closure member is mated to the first closure member is visually represented by a force/pressure gauge to avoid too much pressure onto edge
- 30 of the wound. The tool is also used to cut the guide means when the mating is completed.

A similar closure means is disclosed in US patent 5,342,393 to Stack.

- 35 In US patent 5,531,759 to Kensey et al is described a tool for sealing a percutaneous puncture wound in a vessel with a sealing device, the sealing device

including a substantially rigid anchor member for insertion into the vessel and a sealing member to be pressed to the outside of the vessel.

5 TECHNICAL BACKGROUND

A puncture wound in a blood vessel typically results from a surgical treatment, such as treatment of a vascular disease, such as atherosclerosis.

10 It is known to close such a wound with a two-piece plug device having a distal member that is inserted in the vessel and a proximal member that is tightened towards the distal member with the vessel wall, i.e. the edge of the wound, clamped between the plug members.

15 Such plugs are described in US patents 5,350,399 and 5,342,393, respectively. In both these inventions, however, the retracting means used to transfer a holding force to the intra-arterial closure member is integrally formed with the intra-arterial closure member and is therefore formed of the same material. This limits the possibilities to manipulate the intra-arterial closure member with a tool.

20 Furthermore, tools presently known are complicated to handle in that they require numerous different grips to perform the closing of the wound.

25 They also require the complete attention from the operator in order to avoid misplacement of the closure members. A misplaced closure plug is difficult to remove, and could even call for surgery.

Furthermore, it is essential not to stress the wound too hard in order to avoid rupture of the wound edge. At the same time it is essential to apply a sufficient mating force to the closure members to obtain a leakage-free closing of the wound.

30

Therefore, there is a need for a method and a system that offers a simple and safe closing of a punctured vessel.

SUMMARY OF THE INVENTION

In a first aspect, it is an object of the present invention to provide a tool for a simple and safe securing of a two-piece wound closing plug around the edge of a puncture wound in a vessel in a human or animal body, thereby obstructing blood leakage through the wound.

This object is achieved with the tool device according to claim 1.

The plug is divided into two plug members prior to insertion in the wound. The tool according to the invention includes a compartment for holding the plug members in a folded shape, means for pushing the plug members out of the plug compartment and a gear mechanism for converting a movement of the tool in a direction from the wound to a movement of the plug pushing means to mate and compress the plug members to form a substantially leakage free wound closure plug.

In a second aspect, it is an object of the present invention to provide a plug for use with the tool according to the invention.

This object is achieved with the sealing device according to claim 7.

The plug according to the invention consists of a distal and a proximal plug member. A central bore through the proximal plug member fits on a cylindrical post centrally protruding from the proximal surface of the distal plug member. The surfaces of the central bore and the cylindrical post, respectively, are provided with projections and corresponding recesses to provide a one-way snap fitting. A central through hole is provided in the cylindrical post of the distal plug member to accommodate a flexible retracting means, such as a biodegradable suture.

Since the retracting means is separate from the distal plug member the distal plug member has an improved flexibility within the artery to adapt to the inner artery wall. At the same time, simplified manufacturing of the distal plug member is obtained.

In a third aspect of the present invention, it is an object to provide a simple and safe method for closing a puncture wound in a vessel.

This object is achieved with the method according to claim 9.

According to the method of the invention, a two-piece plug is inserted into the wound with a specially designed tool. A lever is pushed against the wound to push out the distal plug member of the two-piece plug into the vessel. Then, by simply drawing the tool away from the wound the proximal plug member is pushed out of the tool, the plug members are compressed to form a closure plug that encloses the wound edge in a safe grip and finally the tool is completely removed from the wound to leave only a retracting means (such as a suture) attached to the closure plug. The retracting means is easily cut to a desired length.

BRIEF DESCRIPTION OF ATTACHED DRAWINGS

The present invention shall now be described by way of example and with reference to the attached drawings, wherein:

Fig. 1 is a cross sectional view of an embodiment of the components of a plug device for use with the tool of the invention;

Fig. 2 is a cross sectional view of the components of Fig. 1 assembled to form a wound closure plug according to the invention;

Fig. 3 is a cross sectional view of a first embodiment of the tool of the invention, in a state prior to closing a wound.

Fig. 4 is a cross sectional view of the embodiment of Fig. 3, when inserting the distal member of a closure plug.

Fig. 5 is a cross sectional view of the embodiment of Fig. 3, when retracting the introducer from the wound.

Fig. 6 is a cross sectional view of the embodiment of Fig. 3, when mating the proximal plug member with the distal plug member being disposed inside the vessel.

Fig. 7 is a cross sectional view of the embodiment of Fig. 3, when freeing the plug retracting means from the tool.

Fig. 8 is a partly cross sectional view of a second embodiment of the tool of the invention.

Fig. 9 is a detailed view of forces acting on a double gear wheel used in the second embodiment of the tool according to the invention.

Fig. 10 is a cross sectional view of the tool according to fig. 8, seen along the line A-A in Fig. 8.

Fig. 11 is a cross sectional view of the tool according to fig. 8, seen along the line B-B in Fig. 8.

Fig. 12 is a cross sectional view of the tool according to fig. 8, seen along the line C-C in Fig. 8.

Fig. 13 is a cross sectional view of the second embodiment of the tool of the invention, in a state prior to closing a wound.

Fig. 14 is a cross sectional view of the embodiment of Fig. 13, when inserting the distal member of a closure plug.

Fig. 15 is a cross sectional view of the embodiment of Fig. 13, when retracting the introducer from the wound.

Fig. 16 is a cross sectional view of the embodiment of Fig. 13, when mating the proximal plug member with the distal plug member being disposed inside the vessel.

Fig. 17 is a cross sectional view of the embodiment of Fig. 13, when freeing the plug retracting means from the tool.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

First, a plug being preferred for use with the invention shall be described with reference to Fig. 1 and 2.

5 The plug 1 according to Fig. 1 and 2 includes two generally circular main members: a distal plug member 2 and a proximal plug member 3 being made of a flexible biodegradable material, such as lactide/glycolide polymer or polydioxanone. A foldable generally umbrella-shaped disc portion 51 is formed at the distal end of the distal plug member 2, and a similarly generally umbrella-shaped disc portion 52 is
10 formed at the distal end of the proximal plug member 3. The umbrella-shaped disc portion are formed such that their edges are directed toward each other when the plug members are assembled to form a plug.

The distal plug member 2 is designed to be inserted inside a punctured vessel 20,
15 while the proximal plug member 3 is designed to be provided at the outside of the vessel 20.

The distal plug member 2 is provided with a substantially cylindrical central post 7 protruding in a direction out from the vessel, i.e. in the proximal direction, when the plug member 2 is inserted in the vessel. A central bore 8 extends axially
20 through the post 7.

The proximal plug member 3 is provided with a central sleeve section 12 protruding in a direction away from the wound when the plug member 3 is positioned on the
25 outside of the vessel. A central bore 9 extends axially through the sleeve section 12 and is designed to receive the post 7 of the distal plug member 2 when the members are clamped together, as will be described below.

When pressed together, the plug members 2, 3 clamp the edge 21 of the wound in
30 the vessel between the edges of their umbrella-shaped portions 51, 52.

The central bore 9 of the proximal plug member 3 is adapted to be snap fitted onto the post 7 of the distal plug member 2. For that purpose, the bore 9 and the post 7, respectively, are provided with corresponding saw tooth profiles 10, 11. The saw
35 tooth profiles 10, 11 are so arranged that the proximal plug member 3 can be

pressed onto the post 7 of the distal plug member 2 with a force. Thereafter, the plug members can only be separated using a considerable force.

Therefore, no separate retaining means is necessary for holding the plug members
5 securely connected.

The post 7 of the distal plug member 2 has a proximally directed end surface 14. Similarly, the sleeve 12 of the proximal plug member 3 has a proximally directed end surface 13.

10 A string shaped retracting means 6, preferably a suture, is thread through the bore 8. The end of the suture 6 is prevented from passing through the bore when a tension force is applied to it with an enlarged portion. The enlarged portion could, for example, be formed by attaching a small amount of a plastic material, but the
15 simple way of providing a knot, as shown in Fig. 1 and 2, is preferred.

In order to avoid that the suture will slip out of the bore and into the vessel, subsequent to the closing of the wound as will be explained later, it should also be fixed to the bore. This could be achieved by clamping means arranged in or near the
20 bore, but it is preferred to attach the suture in the bore 8 with a small amount of an adhesive (not shown). Although adhesive alone could be used for securing the suture to the bore, the use of the knot is preferred for safety reasons.

It should be noted that although the closure plug and the retracting means
25 described above are suited for use with the tool of the invention, as will be described in the following, they could be used for closing a puncture wound in a vessel also when any other suitable insertion tool is used.

A first embodiment of an inserting tool 101 according to the invention shall now be
30 described with reference to Fig. 3 - 7. It should be noted that in order to make the figures easy to read, a complete set of referral numbers are not provided in each figure.

It is preferred to use the tool to insert a closure plug as disclosed above, but it
35 should be noted that any plug design suitable to cooperate with the inserting tool could be inserted with the tool of the invention. The reason for preferring the plug

according to the present invention is that the use of a separate retracting means, such as a suture, as will be described below provides an improved flexibility of the distal plug member 2 to adapt to the inner wall of the vessel. The use of a suture is also advantageous for performing the wiring in the gear mechanism, as will be described below.

Furthermore, the use of generally umbrella-shaped plug members is advantageous in that an even pressure is applied to the wound edge, thereby reducing the risk for wound edge rupture. The disk shape of the plug members also provides improved possibility to achieve a non-leaking closure. However, the present invention is adaptable for use with other types of plug members, such as those described in US patent 5,531,759.

The inserting tool should be used with an introducer 23. Any introducer being well known in the field of surgical treatment through a blood vessel could be used provided that a fitting 31 of the inserting tool 101 is adapted to a corresponding fitting 26 of the introducer 23 (or is coupled with any suitable separate means, such as clamps). Also, the dimensions of the inserting tool components should be adapted to the introducer, as will be understood from the following description. In Fig. 3 the skin of the patient is indicated with the referral number 24.

As is shown in Fig. 3, the inserting tool comprises an elongated casing 30 enclosing a gear mechanism 32, an outer feeding means 33, an inner feeding means 34, a proximal plug member 3, a distal plug member 2 and a suture 6 (forming a retracting means). The wiring of the suture 6 through the plug members 2, 3 is clearly shown in Fig. 1 and 2.

An elongated opening 35 extends through the casing 30 in the axial direction. An insertion lever 36 extends through the opening 35. The insertion lever is slideable in the opening, and is connected to the gear mechanism 32 inside the casing 30, as will be described. Therefore, when the insertion lever is pushed forward it acts as a pusher means for moving the gear mechanism.

The outer feeding means 33 has a through bore extending axially. The inner feeding means 34 is inserted into the bore of the outer feeding means 33 for axial

movement. A similar through bore extends axially through the inner feeding means 34 for accommodating the suture 6 to move axially therein.

With reference to Fig. 4 and 5, the gear mechanism 32 comprises a pulley spacer member 37, for holding the pulley 38 at a distance from the proximal end of the bore through the outer feeding means 34. The pulley spacer member 37 is fixedly attached to the proximal end of the outer feeding means 33, and a bore (not shown) through the pulley spacer member 37 is positioned to form an extension of the bore through the outer feeding means such that the inner feeding means 34 can move freely through the pulley spacer member 37. A first pulley 38 is rotatably attached to the proximal end of the pulley spacer member 37.

The gear mechanism 32 also comprises a clamping block 39, at its distal end fixedly attached to the inner feeding means 34 by means of a bore (not shown) in the clamping block 39 such that the suture can move freely through the clamping block. A second pulley 40 is rotatably attached to the clamping block 39, and is substantially rotating in the same plane as the first pulley 38.

A first brake means 41, consisting of a spring-loaded brake shoe 42, is mounted on the clamping block 39. A second brake means 43, consisting of a spring loaded brake shoe 44, is mounted on the interior part of the insertion lever 36.

The suture 6, having a knot in its distal end so that it does not slip through the bore of the distal plug member 2, runs through the distal plug member 2, through the inner feeding means 34, out from the clamping block 39 where the suture is held in the first brake means 41, around the first pulley 38, back towards the clamping block, around the second pulley 40 to finally be held by the second brake means 43 of the insertion lever 36. The suture is stretched in order to urge the post 7 end surface 14 of the distal plug member 2 against the inner feeding means 34.

The proximal plug member 3 is disposed around the inner feeding means 34 to move along it, but is restricted from moving in the proximal direction by the end of the outer feeding means 33.

The distal end of the casing has a tapered section 45. Therefore, the mouth 46 at the distal end of the tool is more narrow than the outer diameters of the plug

members, respectively. However, due to the shape of the plug members and the flexibility of their material they will collapse if pressed through the tapered section 45 out of the mouth 46.

- 5 Before use of the tool, the gear mechanism together with all components attached thereto is withdrawn towards the proximal end of the casing 30, as shown in Fig. 3.

An embodiment of a method for closing a wound in a vessel, utilizing the embodiment of an insertion tool as described above, shall now be described.

10

In a first step of the method of the invention, as shown in Fig. 3, the insertion tool 101 is coupled to an introducer 23 being positioned in the wound in the vessel 20.

15
20

In a second step of the method of the invention, as shown in Fig. 4, the insertion tool casing 30 is held essentially stationary with respect to the wound while the insertion lever 36 is pushed towards the wound. The insertion lever 36 abuts against the clamping block 39 to push the clamping block and the pulley spacer member 37 and, consequently, the inner and the outer feeding means 33, 34 towards the wound. Thereby, the plug members 2, 3 are pressed into the tapered section 45 of the casing 30 to collapse to a diameter allowing them to be pushed through the introducer 23.

The length of the opening 35 in which the insertion lever 36 moves, as well as the lengths of other components of the insertions tool 101, are selected to suit the length of the introducer 23 such that when the insertion lever reaches the distal end of the opening to be stopped there, the distal plug member 2 exits out of the introducer 23.

25 When the distal plug member 2 exits from the introducer 23 it unfolds inside the vessel 20. Thereby, the operator is able to feel a "snap", being a signal that the distal plug member 2 is properly inserted.

30 In a third step of the method of the invention, as shown in Fig. 5 and 6, the insertion tool 101 together with the introducer 23 is withdrawn from the wound with a force F_1 to mate the plug members 2, 3. During this step the distal plug member 2 abuts against the inside of the vessel wall 21 to cover the inside of the

35

edge of the puncture. The force F_1 should be controlled by selecting the braking force of the second brake means 43, to be low enough not to rupture the vessel wall around the puncture wound. A typical force for closing a wound in the femoralis artery, which is an artery in which surgical puncture wounds often are opened, without rupturing the vessel is 2 N.

During the withdrawal the suture is stretched around the first pulley 38 and the second pulley 40 and is held at its proximal end by the clamping force of the second brake means 43. The first brake means 41 serves to keep the clamping block 39, and consequently also the inner feeding means 34, at place with respect to the suture 6. The breaking force of the first brake means is adjusted to be the same as the breaking force of the second brake means.

The distance between the second brake means 43 and the second pulley 40 is constant since the insertion lever 36 abuts the clamping block 39. Therefore, the first pulley 38 is drawn towards the second pulley 40. In this movement, the first pulley 38 pushes the pulley spacer member 37, and consequently the outer feeding means 33 and the proximal plug member 3, towards the distal plug member 2.

The snap fitting of the plug elements is designed to require a snapping force of the same order as the force of withdrawal of the tool, that force being transferred to the proximal plug member as described above. Since the gear ratio of the gear mechanism according to the present invention is approximately unity, the plug members are mated with a force substantially the same as the force with which the tool is drawn away from the patient. The brake means 41, 43 limit this force to prevent it from being higher than the strength of the vessel. Therefore, the saw tooth profile should be designed to allow for mating of the plug members with a force somewhat less than the suture breaking force applied by the brake means.

The mating of plug members 2, 3 continues until the first pulley 38 and the pulley spacer member 37 runs into the second pulley 40 and the clamping block 39, as shown in Fig. 6.

In a fourth step of the method of the invention, as shown in Fig. 7, the insertion tool 101 together with the introducer 23 is further withdrawn from the patient to finally remove the tool from the wound.

During this continued withdrawal of the tool casing 30 the insertion lever 36 is urged to stretch the distal suture end. The braking force of the second brake means 43 will not be able to hold the suture 6 when the withdrawing force exceeds said braking force, and consequently the suture will become free from the insertion lever. Continued withdrawal of the casing 30 will result in the same effect at the first brake means 41, thereby leaving the suture free from the tool. The suture remains protruding out from the skin end of the wound, and may be cut to a proper length.

It should be noted that the suture acts as a force transmitting means only, and is not used for holding the plug member together after mating or for pressing any of the plug members towards the vessel wall.

A second embodiment of the tool of the invention 102 shall now be described with reference to Fig. 8 - 12.

As seen in Fig. 8, a casing 130, an introducer fitting 131, a tapered end section 145 of the casing 130, a mouth 146 at the distal end of the tool 102 corresponds to the first embodiment described above. Also, the plug members 2, 3, the suture 6 and the outer and the inner feeding means 133, 134 are initially disposed in the casing 130 as for the first embodiment above. The outer and inner feeding means runs with a clearance through a bore 173 in the casing, said bore 173 being narrow enough to act as a guide that prevents the feeding means from excessive bending in a case where they are formed from a highly flexible material, such as a thermoplastic. Such highly flexible material for forming the feeding means is advantageous in that it improves the flexibility of the feeding means, thereby providing higher freedom of movement within the wound.

The inserting tool 102 comprises a gear mechanism 132 of a different design than the gear mechanism 32 of the first embodiment. According to the second embodiment, the proximal end of the inner feeding means 134 is formed as a block section 160 protruding towards the viewer of Fig. 8, while the proximal end of the outer feeding means 133 is formed as a plate section 161 extending axially with respect to the outer feeding means and perpendicularly with respect to the block

section 160. The block section 160 extends through an axial opening 162 in the plate section 161 to be axially movable in the opening 162.

The longitudinal sides of the plate section 161 of the outer feeding means 133 are provided with cog profiles 163a, 163b.

An upper plate 164 in which a substantially T-shaped opening 165 is formed is positioned above, and substantially parallel with, the plate section 161 such that the block section 160 extends through the "leg" of the T-opening. A wire spring 166 is biased into the T-opening, transverse to the "leg", and runs through a small hole in the block section 160 to press the upper plate 164 towards the block section 160.

Two double gear wheels 168a, 168b, each one having a small gear ring 180 and a large gear ring 181 (as seen in Fig. 9) being fixed with respect to each other, are rotatably mounted in the upper plate 164. The gear wheels 168a, 168b are disposed one at each side of the plate section 161 such that the small gear ring 180 of each gear wheel engages the cog profile 163a, 163b of the respective side of the plate section 161.

A cover 150 being axially slideable in guides 169 in the casing 130 covers the plate section 161, the upper plate 164 and their associated components, as shown in Fig. 8, 10 and 11. Two inner gear racks 170a, 170b, one at each inner side of the cover 150, runs axially inside the cover. When the cover is mounted on the casing, the large gear rings of the double gear wheels 168a, 168b are engaged with the gear racks 170a, 170b, respectively.

The upper plate 164 abuts against an inner seat 171 of the cover 150. When the cover 150 is pushed forward with respect to the casing 130, i.e. in a distal direction, it pushes the upper plate 164 forward as well, and brings with it the other components of the gear mechanism. Therefore, when the cover is pushed forward it acts as a pusher means for moving the gear mechanism.

As shown in Fig. 12, the proximal end of the suture 6 ends in a small recess in the substantially T-shaped opening 165 of the upper plate 164, and is stretched and clamped between the block section 160 of the inner feeding means 134 and the upper plate 164 by means of the wire spring 166. The bias of the wire spring is

selected to apply a suture holding force lower than the rupture pull force of the vessel. The suture holding force corresponds to the force with which the tool is drawn away from the wound during use.

5 It should be noted that it is possible to design a gear mechanism having one double gear wheel, cog profile and gear rack set only, if the other set it replaced by a guide means to allow for a proper linear movement. However, the embodiment being described herein with reference to Fig 8 - 17 is presently assessed to provide a more reliably performance.

10 A second embodiment of the method for closing a wound in a vessel, utilizing the second embodiment of the insertion tool 102, shall now be described with reference to Fig. 13-17.

15 In the first step of the second embodiment of the method of the invention, as shown in Fig. 13, the insertion tool 102 is coupled to an introducer 123 being positioned in the wound and extending through the wall of the vessel.

20 In the second step of the second embodiment of the method of the invention, as shown in Fig. 14, the insertion tool casing 130 is held essentially stationary with respect to the wound while the cover 150 is pushed towards the wound. As described above, when pushed forward, the cover 150 brings the upper plate 164 forward as well. As both the inner and the outer feeding means 133, 134 are coupled to the upper plate they are pushed through the introducer 123 towards the
25 wound. Thereby, the plug members 2, 3 are pressed into the tapered section 145 of the casing 130 to collapse to a diameter allowing them to be pushed through the introducer 123.

30 The cover 150 is pushed forward (i.e. in the distal direction) until the distal plug member 2 exits from the introducer 123 to unfold itself inside the vessel 20. When the distal plug member 2 unfolds this is registered by the operator as a "snap".

As for the first embodiment, the dimensions of the parts involved are selected to suit the length of the introducer 123.

In the third step of the second embodiment of the method of the invention, as shown in Fig. 15 and 16, the insertion tool 102 together with the introducer 123 is withdrawn from the wound with a force F_1 to mate the plug members 2, 3 corresponding to what has been previously described for the first embodiment.

5

However, the gear mechanism 132 of the second embodiment provides a gear ratio higher than unity, thereby enabling the plug members 2, 3 to be mated with a force higher than the withdrawing force of the tool. This shall now be described.

10 As the operator pulls the insertion tool 102 away from the wound subsequent to the unfolding of the distal plug member, the cover 150 abuts against a stopping means, such as a step-shaped edge 172 (see Fig. 12) extending from the casing 130. Therefore, as the casing 130 is pulled further away from the patient, the cover 150 follows this movement while the suture 6 remains stretched to keep the block section 160 at a substantially constant distance from the distal plug member.

15 At the same time, the stretching force in the suture is transferred to the upper plate 164 via the block section 160. However, as the cover 150 and consequently the gear racks 170a, 170b are pushed with the force F_1 with respect to the suture, this force F_1 acts on the large gear ring 181 of each gear wheel 168a, 168b, respectively, to rotate the gear wheels. Due to lever action, this creates a force F_1+F_2 in the small gear rings 180 to act on the cog profiles 163a, 163b of the plate section 161 (see Fig. 9) for driving the plate section in the opposite direction with respect to the tool pulling force, i.e. in the distal direction.

25

Thus, although the casing 130 and the cover 150 are pulled away from the distal plug member 2 with a force F_1 , the plate section 161 strives towards the distal plug member 2 with the force F_1+F_2 . As the plate section 161 moves in the distal direction, the outer feeding means 133 moves with it towards the distal plug member 2.

30

Therefore, the proximal plug means 3 is mated with the distal plug means 2 with the force F_1+F_2 .

In the fourth step of the second embodiment of the method of the invention, as shown in Fig. 17, the tool 102 is further withdrawn from the patient to finally remove the tool from the wound.

5 During this continued withdrawal of the tool, the withdrawing force now acts on the point where the proximal end of the suture 6 is clamped between the upper plate 164 and the block section 160. When the pulling force exceeds the force of the wire spring 166 acting of the suture via the block section, the spring will loose its grip on the suture and the suture will slip out of the inner bore of the inner feeding means
10 of the tool. The suture may then be cut to a proper length.

Using the method and the tool according to the second embodiment of the invention is preferred as compared to the first embodiment since the additional mating force F_2 allows the edges of the wound to be positively clamped between the plug members to ensure a safe closure of the wound even in a case where the material of the plug relaxes somewhat after insertion.

Using the tool of the present invention has many advantages.

20 No ordinary skill is required to ensure that the intra-arterial member of the closure plug is entirely inserted into the vessel, since this is taken care of by designing of the tool with suitable dimensions with respect to the introducer.

The "snap" feeling gives a positive indication to the operator that the intra-arterial
25 member of the closure plug has unfolded properly.

The entire closing procedure is performed by the simple and natural withdrawing movement of the tool from the wound. The operator only has to take care not to withdraw the tool too fast from the wound, thereby exceeding the mechanical
30 response in the gear mechanism.

There is no need for the operator to monitor a force gauge, since the brake means applied to the retracting means are preset to loosen their grip on the retracting means if an excessive withdrawing force is applied. Therefore, the risk of rupturing
35 the vessel is considerably reduced.

CLAIMS

1. A tool (101; 102) for inserting and mating two plug members (2, 3) of a sealing device (1) for closing a wound in the wall of a vessel, one plug member of the sealing device being a distal plug member (2) to be positioned inside the vessel and the other plug member being a proximal plug member (3) to be positioned outside of the vessel, and the distal plug member being provided with an elongated retracting means (6) extending from the distal plug member,
- 10 **characterized in** that the tool comprises a gear mechanism (32; 132) coupled to the retracting means for converting a movement of the tool in a proximal direction away from the wound, when the distal plug member is anchored in the vessel, to a pushing movement for moving the proximal plug member in a direction towards the distal plug member in response to a stretching force (F_1) in the retracting means.
- 15 2. The tool (101; 102) according to claim 1, **characterized in** that the tool comprises a spring-biased coupling means (41; 164, 166) for releasably coupling the retracting means (6) to said gear mechanism (32; 132).
- 20 3. The tool (101; 102) according to claim 2, **characterized in** that the biasing force of said spring-biased coupling means (41; 164, 166) is selected to release the retracting means (6) when the stretching force (F_1) in the retracting means exceeds a selected force attributed to the rupture tension of the wall of vessel.
- 25

4. The tool (101; 102) according to anyone of claims 1 through 3,

characterized in that said tool comprises

an outer feeding means (33; 133) for pushing the proximal plug member (3), said outer feeding means being provided with an axial through bore;

5 an inner feeding means (34; 134) for pushing the distal plug member (2), said inner feeding means being provided with an axial through bore for moveably receiving said retracting means (6), and said inner feeding means being disposed for movement in said bore of said outer feeding means;

10 said gear mechanism (32; 132) being coupled to said inner feeding means and said outer feeding means; and

a pushing means (36, 150) for pushing the gear mechanism (32; 132), the outer feeding means (33; 133) and the proximal plug member (3) with respect to the casing (30; 130) of the tool, in a direction towards the wound.

15 5. The tool (102) according to claim 4

characterized in that said gear mechanism (132) comprises

at least one of a set comprising

a gear rack (170a, 170b) fixed to said pushing means (150),

a cog rail (163a, 163b) connected to said outer feeding means (133),

20 a double gear wheel (168a, 168b) having a small gear ring (180) and a large gear ring (181) fixed with respect to each other, said double gear wheel being rotatably connected to a plate member (164),

said large gear ring (181) being in engagement with said gear rack (170a, 170b) and said small gear ring (180) being in engagement with said cog rail (163a, 163b),

25 and said plate member (164) being arranged to move with said outer feeding means and said plate member releasably holding the retracting means by means of a spring (166), the retracting means being moveably disposed in the bore of said inner feeding means,

30 said set thereby cooperatively arranged to convert a proximal movement of said tool to a distal movement of said outer feeding means when the retracting means is stretched.

6. The tool (101) according to claim 4

characterized in that said gear mechanism (32) comprises

a first pulley (38) attached to said outer feeding means via a spacer member (37);

a second pulley (40) attached to said inner feeding means (34);

5 a first brake means (41) attached to said inner feeding means;

a second brake means (43) attached to said pushing means (36); and

wherein the retracting means (6) is arranged such that it extends from the distal plug member (2) in a proximal direction, through said bore of said inner feeding means (33), through the first brake means (41), around said first pulley (38) to be

10 redirected to a distal direction, around said second pulley (38) to be redirected again to the proximal direction, and through said second brake means (43).

7. A sealing device (1) including a distal resiliently expandable plug member (2) having an elongated retracting means extending centrally from the distal plug member and including a portion (10) for attaching a proximal plug member (3) of the sealing device, the proximal plug member being resiliently expandable and being adapted to be mounted onto the distal plug member to be fixed thereto by means of the attaching portion,

15 **characterized in** that the distal plug member comprises a through bore (8), and a suture (6) is passed through said bore (8) to serve as the retracting means by providing an enlarged portion at one end as a counter when pulling the suture.

8. A system for closing a wound in a punctured vessel,

20 **characterized in** that a sealing device according to claim 7 is inserted and mated by the use of a tool according to anyone of claims 1 through 6.

9. A method for closing a wound in a punctured vessel by inserting and mating two plug members (2, 3) of a sealing device (1), one plug member of the sealing device being a distal plug member (2) to be positioned inside the vessel and the other plug member being a proximal plug member (3) to be positioned outside of the vessel, and the distal plug member being provided with an elongated retracting means (6) extending from the distal plug member, the method including the step of

- positioning the distal plug member (2) inside the vessel with the retracting means (6) being attachable to the tool;

characterized in that it comprises the steps of

- providing a tool (101; 102) comprising a gear mechanism (32; 132) connectable to the retracting means for converting a movement of the tool in a proximal direction away from the wound, to a pushing movement for moving the proximal plug member in a direction towards the distal plug member in response to a stretching force (F_1) in the retracting means when the distal plug member is anchored in the vessel; and

- withdrawing the tool (101; 102) with the retracting means attached thereto to stretch the retracting means, thereby activating the gear mechanism to approach the proximal plug member towards the distal plug member via a feeding means (34; 134).

10. The method according to claim 9, wherein said tool (101; 102) comprises a spring-biased coupling means (41; 164, 166) for releasably coupling the retracting means (6) to said gear mechanism (32; 132).

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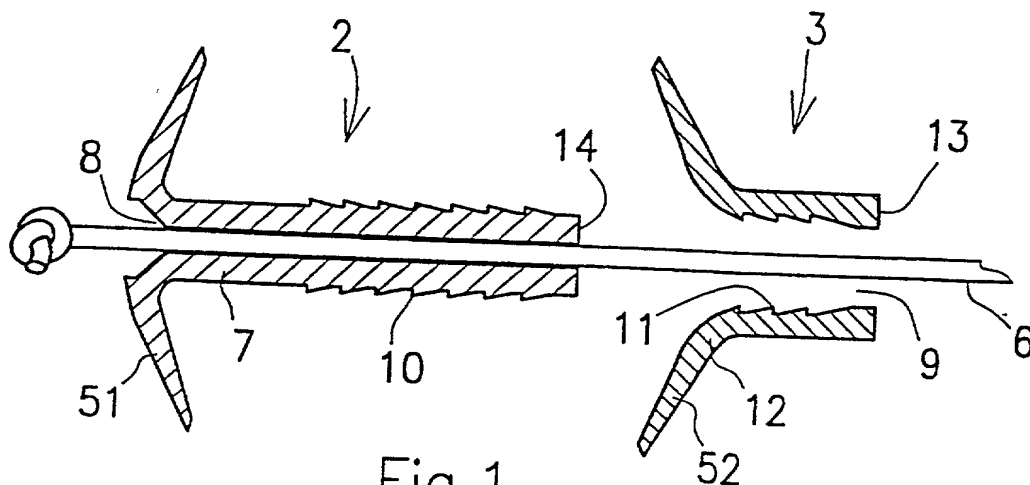


Fig.1

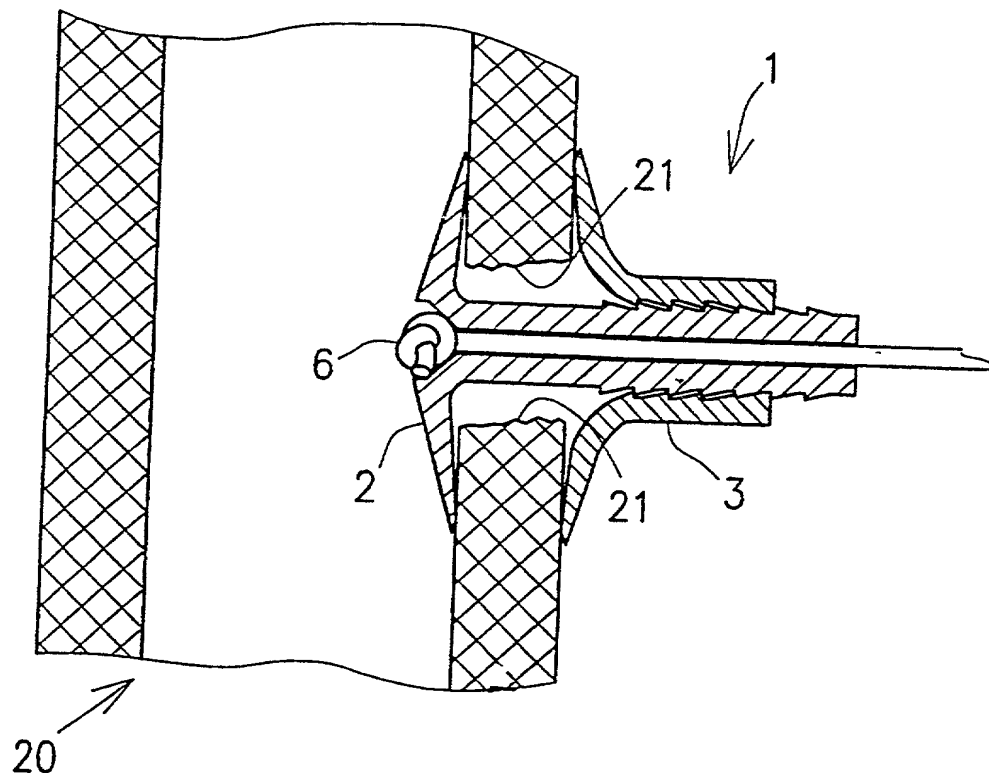
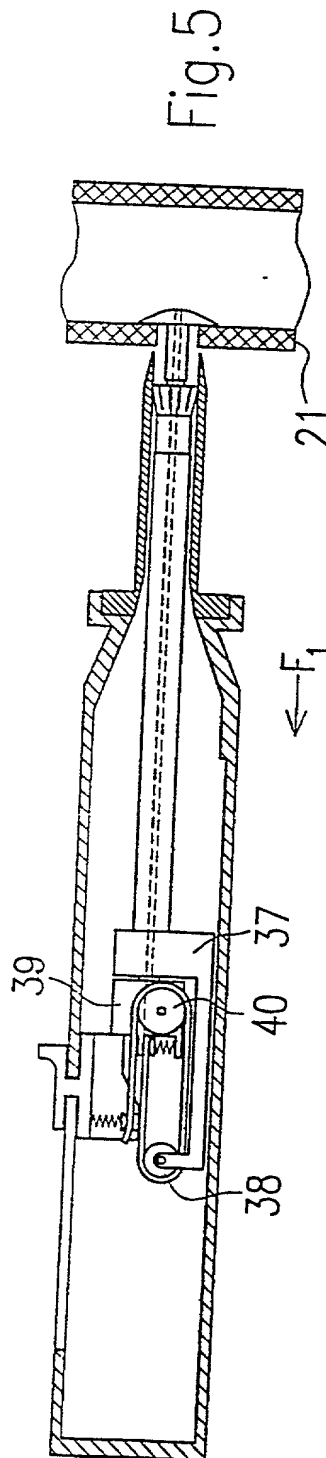
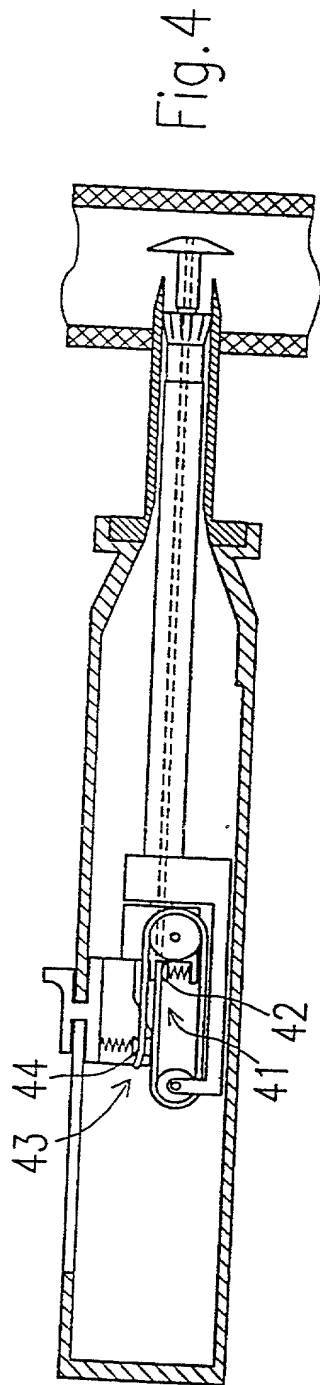
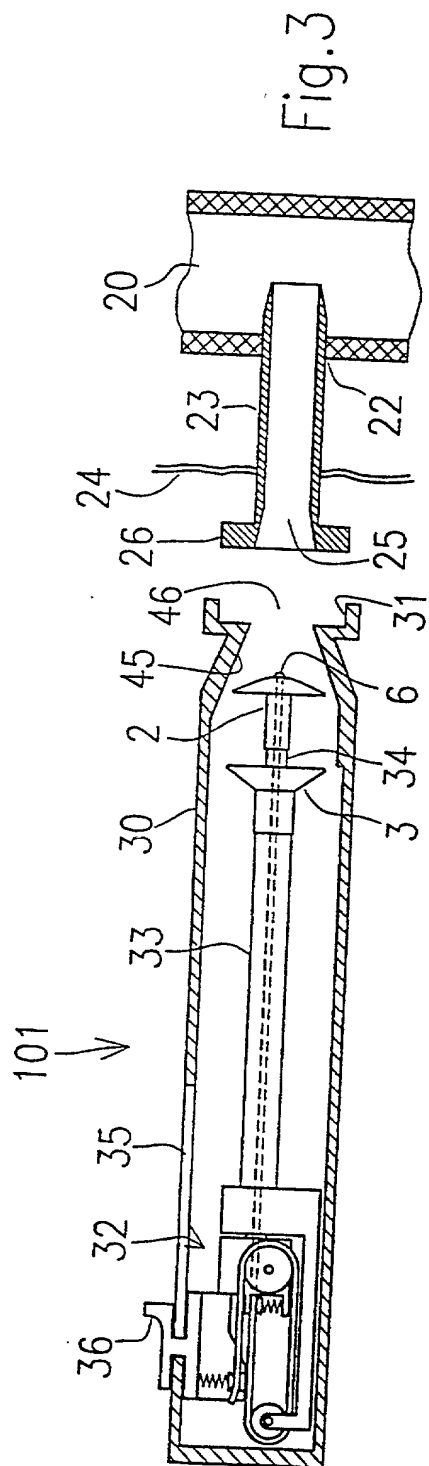


Fig.2

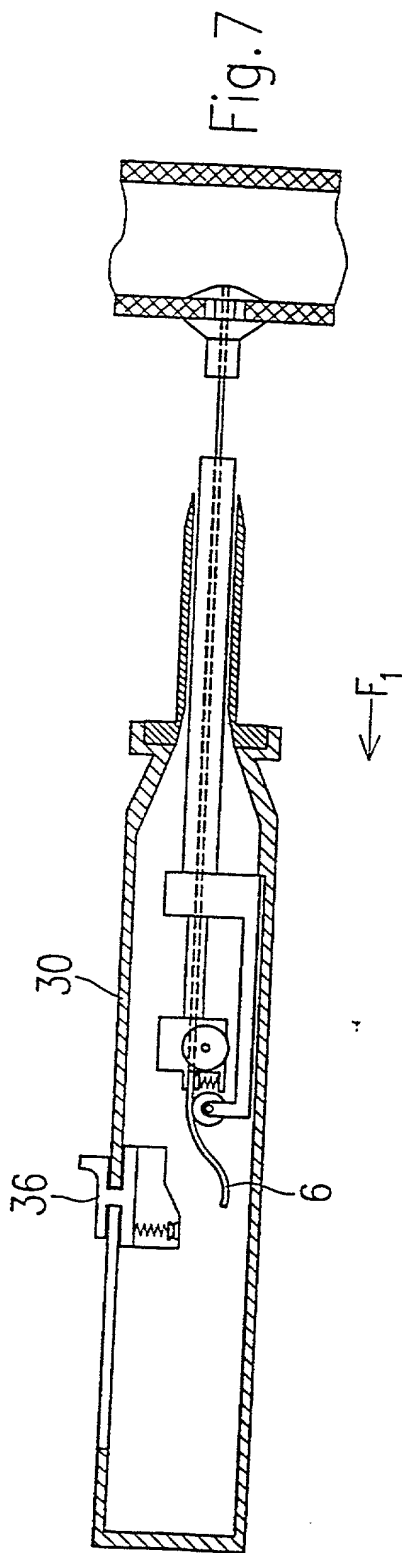
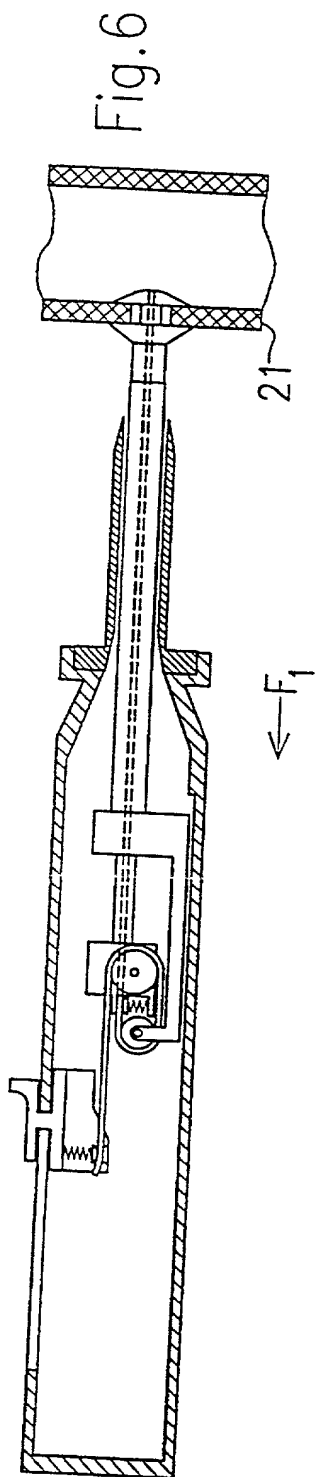
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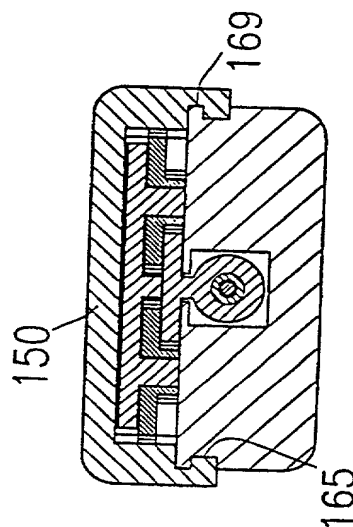
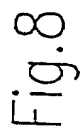


Fig. 10

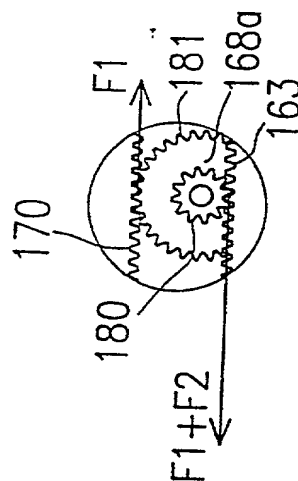


Fig. 9.

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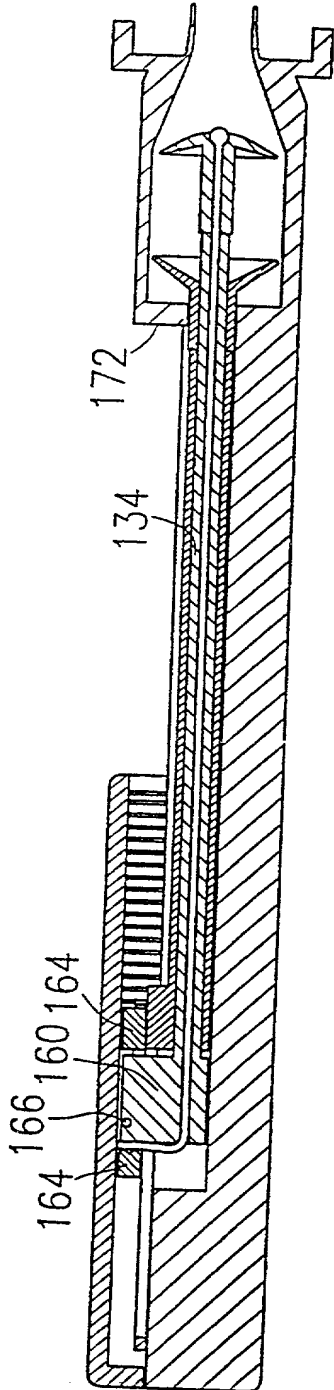


Fig.12

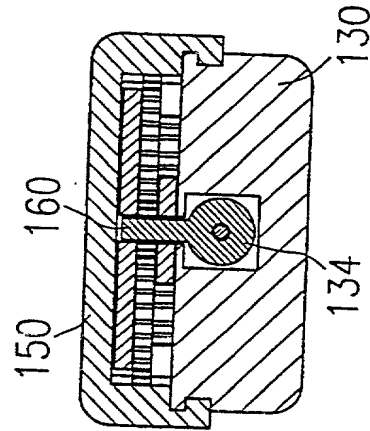
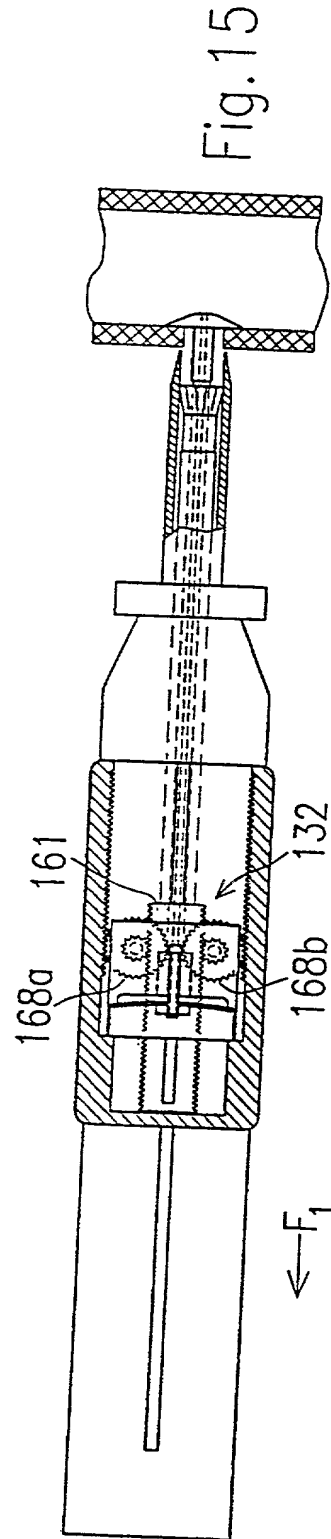
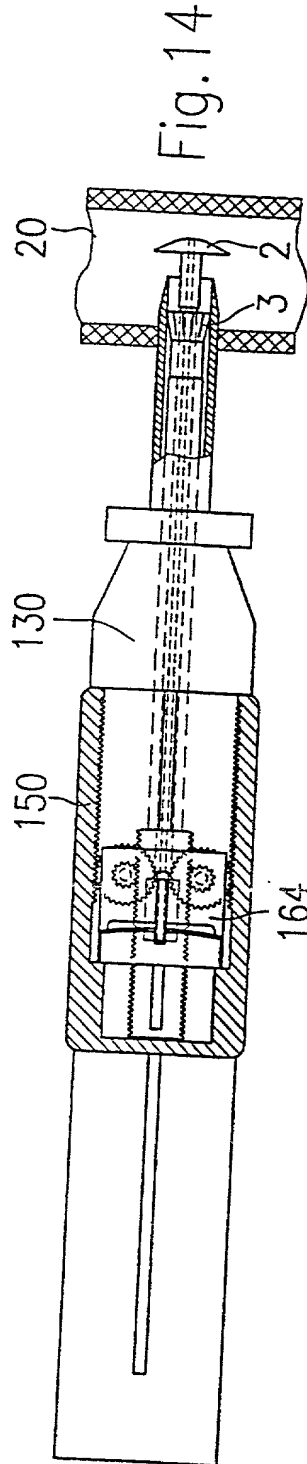
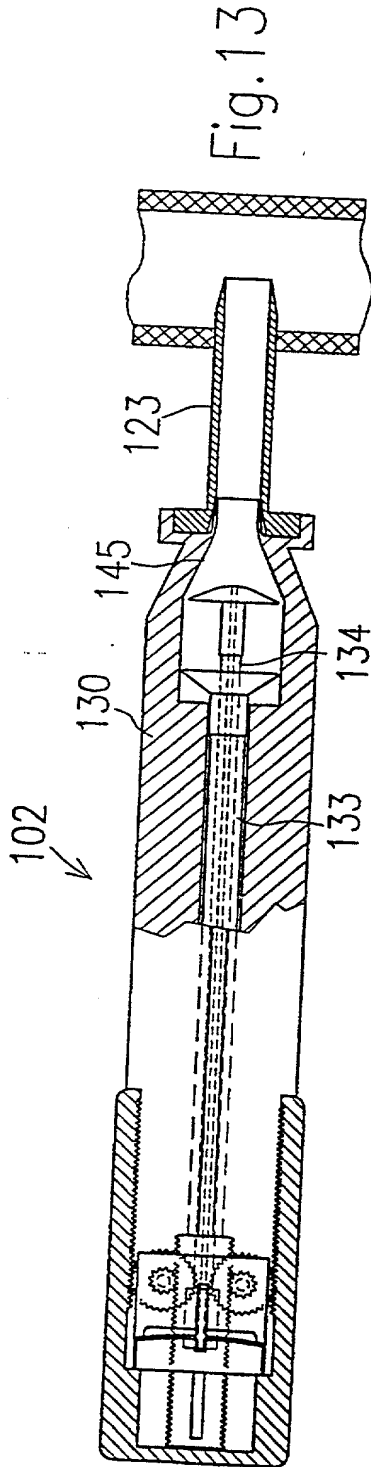


Fig.11

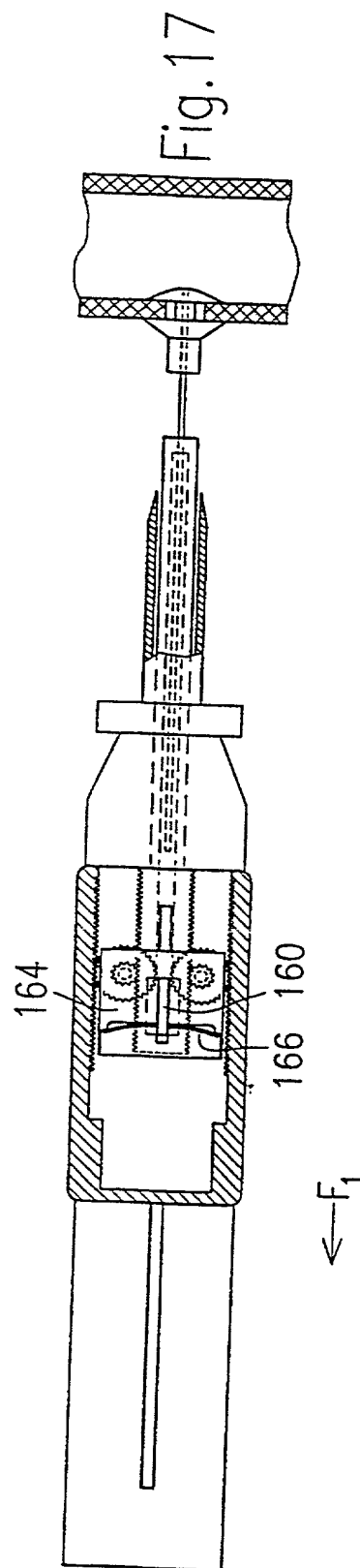
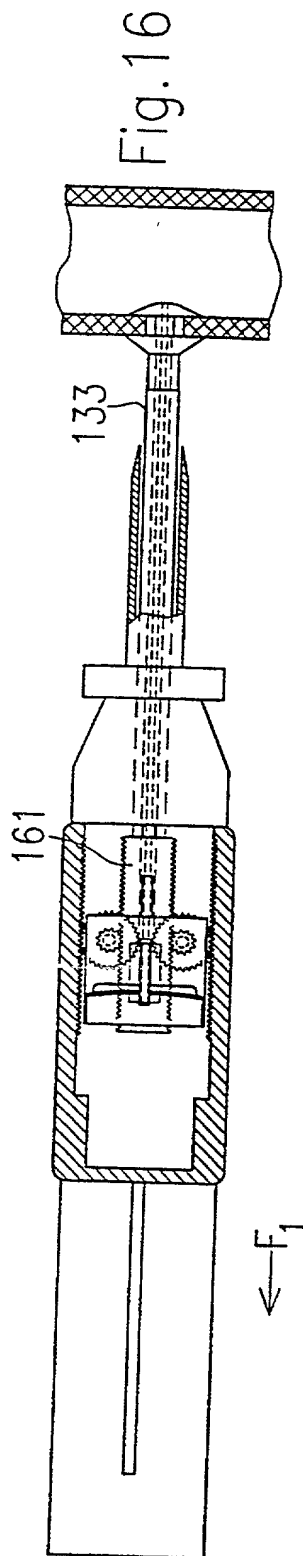
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DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I HEREBY DECLARE:

THAT my residence, post office address, and citizenship are as stated below next to my name;

THAT I believe I am the original, first, and sole inventor (if only one inventor is named below) or an original, first, and joint inventor (if plural inventors are named below or in an attached Declaration) of the subject matter which is claimed and for which a patent is sought on the invention entitled

A TOOL, A SEALING DEVICE, A SYSTEM AND A METHOD FOR CLOSING A WOUND

(Attorney Docket No. 030481-0183)

the specification of which (check one)

 is attached hereto.

 X was filed on June 18, 1999 as United States Application Number or PCT International Application Number PCT/SE99/01114 and was amended on _____ (if applicable).

THAT I do not know and do not believe that the same invention was ever known or used by others in the United States of America, or was patented or described in any printed publication in any country, before I (we) invented it;

THAT I do not know and do not believe that the same invention was patented or described in any printed publication in any country, or in public use or on sale in the United States of America, for more than one year prior to the filing date of this United States application;

THAT I do not know and do not believe that the same invention was first patented or made the subject of an inventor's certificate that issued in any country foreign to the United States of America before the filing date of this United States application if the foreign application was filed by me (us), or by my (our) legal representatives or assigns, more than twelve months (six months for design patents) prior to the filing date of this United States application;

THAT I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above;

THAT I believe that the above-identified specification contains a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, and sets forth the best mode contemplated by me of carrying out the invention; and

THAT I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I HEREBY CLAIM foreign priority benefits under Title 35, United States Code § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number	Country	Foreign Filing Date	Priority Claimed?	Certified Copy Attached?

I HEREBY CLAIM the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

U.S. Provisional Application Number	Filing Date

I HEREBY CLAIM the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Application Number	Parent Filing Date	Parent Patent Number

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to have full power to prosecute this application and any continuations, divisions, reissues, and reexaminations thereof, to receive the patent, and to transact all business in the United States Patent and Trademark Office connected therewith.

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I UNDERSTAND AND AGREE THAT the foregoing attorneys and agents appointed by me to prosecute this application do not personally represent me or my legal interests, but instead represent the interests of the legal owner(s) of the invention described in this application.

I FURTHER DECLARE THAT all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1-00

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Date	<u>2002-02-11</u>